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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,202	09/29/2000	David Bar-Or	4172-3	3734

22442 7590 05/02/2003

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	9

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/678,202	Applicant(s) BAR-OR ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 85, 105, 109, 113, 117, 140, 163, 186-210, 234, 238, 242, 265, 288-311, 332, and 352 have been cancelled. Claims 1-58 are now pending.

Applicants' election of Groups 1 and 2 is acknowledged. This election is non-responsive. However, the restriction is now revised, as set forth below.

Applicants elected "specie" is also acknowedged, i.e., the tetrapeptide D-A-H-K. (The assumption is that each of these is an "L" amino acid; if this is not intended, applicants should identify which of these amino acids are "D"). Applicants have asserted that the "elected specie" is encompassed by each of claims 1-31. However, this is not correct. For example, claim 12 does not encompass this tetrapeptide. The tetrapeptide D-A-H-K corresponds to the case in which "n" is zero and Xaa3 is lysine, or else P2 is lysine, and "n" is one. At most, P2 is a single amino acid; a single amino acid, however, is not a "sequence". The term "sequence" implies the presence of at least two amino acids. For similar reasons, claim 13 does not encompass the elected specie. Claims 18-20 also do not encompass the elected specie, since the elected specie is limited to "L" amino acids only.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121 (subgenera G1 - G5 remain as defined previously; the numbering begins with #34 to avoid conflict with previous groups):

34. Claims 1-31, drawn to a method of reducing the damage done by "ROS" in an

animal, wherein the compounds are limited to G2.

35. Claims 1-31, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G1.

36. Claims 32-55, 57, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G2.

37. Claims 32-55, 57, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G1

38. Claim 56, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G2.

39. Claim 56, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G1.

40. Claim 58, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G2.

41. Claim 58, drawn to a method of reducing the damage done by "ROS" in an animal, wherein the compounds are limited to G1.

The claimed inventions are distinct.

As indicated previously, subgenus "G1" and "G2" have been created. Applicants have argued that they do not understand the full extent of what might be encompassed by G1

versus what is encompassed by G2. As indicated previously, within "G1", the structure of the compound cannot be determined without consulting a document which has been "incorporated by reference". By way of example, the term "albumin" is recited on page 3, line 11; human, rat and bovine albumin are disclosed on page 14, line 20. Certainly, the protein chemist of ordinary skill is well acquainted with this protein. If a dependent claim were added which recited a method of reducing the damage done by "ROS" in a human, comprising the step of administering human albumin, such a claim would more appropriately fall within "G2" than G1. But suppose (as a hypothetical) that somewhere in the specification there is a reference which discloses modified albumins in which various amino acids have been deleted and/or changed, such that the resulting albumin does not occur in humans, or any other animal for that matter. If a claim were added which recited the sequence of that modified albumin, such a claim would belong in "G1". As another example, on page 14 (last line) USP 5,928,955 is disclosed. Within this patent is SEQ ID NO: 114 (cols 67-68), the first 10 amino acids of which are the following:

K-Y-H-C-T-D-C-D-Y-T

It does not appear that this peptide is diclosed in the instant specification. Suppose that applicants were to submit the following claim:

> *A method of reducing the damage done to cardiac tissue by "ROS" comprising administering to a patient suffering from cardiac ischemia a peptide of the following sequence:*
>
> *K-Y-H-C-T-D-C-D-Y-T... ...(etc.)*

Applicants could argue that this is not new matter because the contents of the patent which disclosed this peptide have been "incorporated by reference". (The examiner does not now argue that this would be new matter, or that it would not). If such a claim were submitted, it would fall within the scope of G1, rather than G2, since this peptide sequence could not have been envisioned from a reading of the specification. This example underscores another point, which is that of examining burden. A very considerable number of documents have been "incorporated by reference"; to fully examine all possible embodiments, every molecule in every document that has been "incorporated by reference" would have to be scrutinized, and possible claims constructed (by the examiner), and then every embodiment would then have to be searched to find a combination of references which would link the disclosed compound to the claimed method. Such an examination would be unduly burdensome. Applicants have argued that subgenera "G1" and "G2" do not constitute a proper basis for restriction, and that the examiner can impose a restriction after the FAOM (first action on the merits). However, in the absence of a restriction based on these two subgenera, applicants could argue (after the FAOM) that the examiner has examined all possible embodiments, or should have, and that it would be inappropriate to withdraw from consideration embodiments which have been (or should have been) fully searched. By imposing this restriction, the examiner makes no representation that all

embodiments have been fully searched, at least for the case where one of the groups drawn to "G2" has been elected. On the other hand, if applicants elect one of the groups drawn to "G1", the examiner could argue that the claimed invention has not been fully disclosed, and that a further restriction (after the FAOM) will be justified on that basis.

Applicants have argued that they do not understand the distinction between (a) an invention that can be discerned from the reading of a specification, and (b) an invention that cannot be determined without consulting one or more documents in addition to the specification. Examples have been given above, which should help clarify matters. However, if this is still not clear applicants are invited to contact the examiner for further discussion. Given the willingness of the examiner to answer specific questions regarding the distinction between the two groups, a statement that the restriction is not understood is not a sufficient reason for declining to elect an invention.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect several disclosed species (as set forth below) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

I. In the event that Group 34 is elected, the peptide species election (D-A-H-K) will remain in force. Additional elections are required, as set forth below:

- A specific kind of "damage" that one would be endeavoring to mitigate. Some possibilities for the type of damage would include the following: cleavage of DNA, oxidation of side chains on a specific protein, damage to a specific tissue, or damage to a specific cell type.

- the animal (a) has undergone radiation therapy, (b) will undergo radiation therapy, or (c) neither (a) nor (b);

- the animal (a) has undergone open-heart surgery, (b) will undergo open-heart surgery or (c) neither (a) nor (b);

- the animal (a) has undergone organ transplant, (b) will undergo organ transplant or (c) neither (a) nor (b)

- the animal is (a) exhibiting symptoms of ischemia, or (b) not exhibiting symptoms of ischemia;

- the peptide is (a) administered so as to meet one of the criteria of claim 24, or (b) not administered so as to meet one of the criteria of claim 24;

- A specific illness with which the animal is afflicted, such as one of those recited on pages 32-33 of the specification.

II. In the event that Group 35 is elected, the following species elections are required:

- A specific peptide that falls within the scope of Group 35. (Note that the peptide D-A-H-K does not fall within the scope of Group 35.

- A specific kind of "damage" that one would be endeavoring to mitigate. Some possibilities for the type of damage would include the following: cleavage of DNA, oxidation of side chains on a specific protein, damage to a specific tissue, or damage to a specific cell type.

- the animal (a) has undergone radiation therapy, (b) will undergo radiation therapy, or (c) neither (a) nor (b);

- the animal (a) has undergone open-heart surgery, (b) will undergo open-heart surgery or (c) neither (a) nor (b);

- the animal (a) has undergone organ transplant, (b) will undergo organ transplant or (c) neither (a) nor (b);

- the animal is (a) exhibiting symptoms of ischemia, or (b) not exhibiting symptoms of ischemia;

- the peptide is (a) administered so as to meet one of the criteria of claim 24, or (b) not administered so as to meet one of the criteria of claim 24;

- A specific illness with which the animal is afflicted, such as one of those recited on pages 32-33 of the specification.

. . . .

III. In the event that Group 36 or 37 is elected, the following species elections are required:

- A specific, fully defined molecule that falls within the scope of Group 36.

- In addition to electing a specific, fully defined molecule that falls within the scope of Group 36, an additional "specie" is one of the following: (a) a substituent on P1 that increases the lipophilicity of the peptide without altering the ability of P1 to bind metal ions; (b) a substituent on P1 that protects the peptide from proteolytic enzymes without altering the ability of P1 to bind metal ions; (c) a substituent on P1 which is a non-peptide, metal-binding functional group that improves the ability of the peptide to bind metal ions. In addition to the foregoing, an additional "specie" is one of the following: (d) a substituent on P2 that increases the lipophilicity of the peptide without altering the ability of P1 to bind metal ions; (e) a substituent on P2 that protects the peptide from proteolytic enzymes without altering the ability of P1 to bind metal ions; (f) a substituent on P2 which is a non-peptide, metal-binding functional group that improves the ability of the peptide to bind metal ions; or (g) a statement that within the elected specie, P2 is not "substituted".

- A specific kind of "damage" that one would be endeavoring to mitigate. Some possibilities for the type of damage would include the following: cleavage of DNA,

oxidation of side chains on a specific protein, damage to a specific tissue, or damage to a specific cell type.

- the animal (a) has undergone radiation therapy, (b) will undergo radiation therapy, or (c) neither (a) nor (b);

- the animal (a) has undergone open-heart surgery, (b) will undergo open-heart surgery or (c) neither (a) nor (b);

- the animal (a) has undergone organ transplant, (b) will undergo organ transplant or (c) neither (a) nor (b);

- the animal is (a) exhibiting symptoms of ischemia, or (b) not exhibiting symptoms of ischemia;

- the peptide is (a) administered so as to meet one of the criteria of claim 24, or (b) not administered so as to meet one of the criteria of claim 24;

- A specific illness with which the animal is afflicted, such as one of those recited on pages 32-33 of the specification.

. . . .

IV. In the event that Group 38 or 39 is elected, the following species elections are required:

- A specific, fully defined molecule that falls within the scope of Group 38 or 39 (respectively);

- In addition to electing a specific, fully defined molecule that falls within the scope of Group 36, an additional "specie" to be elected is one of the following: (a) a substituent on P2 that increases the lipophilicity of the peptide without altering the ability of P1 to bind metal ions; (b) a substituent on P2 that protects the peptide from proteolytic enzymes without altering the ability of P1 to bind metal ions; (c) a substituent on P2 which is a non-peptide, metal-binding functional group that

improves the ability of the peptide to bind metal ions;

- A specific kind of "damage" that one would be endeavoring to mitigate. Some possibilities for the type of damage would include the following: cleavage of DNA, oxidation of side chains on a specific protein, damage to a specific tissue, or damage to a specific cell type;

- the animal (a) has undergone radiation therapy, (b) will undergo radiation therapy, or (c) neither (a) nor (b);

- the animal (a) has undergone open-heart surgery, (b) will undergo open-heart surgery or (c) neither (a) nor (b);

- the animal (a) has undergone organ transplant, (b) will undergo organ transplant or (c) neither (a) nor (b);

- the animal is (a) exhibiting symptoms of ischemia, or (b) not exhibiting symptoms of ischemia;

- the peptide is (a) administered so as to meet one of the criteria of claim 24, or (b) not administered so as to meet one of the criteria of claim 24;

- A specific illness with which the animal is afflicted, such as one of those recited on pages 32-33 of the specification.

. . . .

V. In the event that Group 40 is elected, the peptide species election (D-A-H-K) will remain in force. An additional specie election is required, namely a specific kind of "damage" that one would be endeavoring to mitigate. Some possibilities for the type of damage would include the following: cleavage of DNA, oxidation of side chains on a specific protein, damage to a specific tissue, or damage to a specific cell type.

. . . .

VI. In the event that Group 41 is elected, two species elections are required: (a) a specific

peptide that falls within the scope of Group 41, and (b) a specific kind of "damage" that one would be endeavoring to mitigate. Some possibilities for the type of damage would include the following: cleavage of DNA, oxidation of side chains on a specific protein, damage to a specific tissue, or damage to a specific cell type.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

✺

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1653